need not include effectiveness data as specified by §514.111 of this chapter, but may require bioequivalency information. Applications must be accompanied by a written commitment to undertake the human safety studies required by FDA.

(e) *Conditions of uses.* As a 25-percent sulfaquinoxaline soluble powder.

(1) For the control and treatment of outbreaks of coccidiosis in cattle and calves caused by *Eimeria bovis* or *E. zurnii.*

(2) Give one teaspoon of 25 percent sulfaquinoxaline soluble powder for each 125 pounds of body weight for 3 to 5 days as a drench.

(f) *Limitations.* For control of outbreaks of disease, medication should be initiated as soon as the diagnosis is determined. Consult a veterinarian for diagnosis. Do not give to cattle within 10 days of slaughter for food. Not for use in lactating dairy cattle.

[48 FR 3964, Jan. 28, 1983, as amended at 55 FR 29843, July 23, 1990; 59 FR 33197, June 28, 1994]

§ 520.2330 Sulfisoxazole tablets.

(a) *Specifications.* Each tablet contains 260 milligrams (4 grains) of sulfisoxazole.

(b) *Sponsor.* See No. 000856 in §510.600(c) of this chapter.

(c) *Conditions of use*—(1) *Amount.* Administer one tablet orally per 4 pounds of body weight.[1]

(2) *Indications for use.* Use in dogs and cats as an aid in treatment of bacterial pneumonia and bacterial enteritis when caused by organisms sensitive to sulfisoxazole.[1]

(3) *Limitations.* Repeat dosage at 24-hour intervals until 2 to 3 days after disappearance of clinical symptoms. (Administration of one-half daily dosage at 12-hour intervals or one-third daily dosage at 8-hour intervals will provide a more constant blood level.) Provide adequate supply of drinking water. If symptoms persist after using this preparation for 2 or 3 days, consult a veterinarian.[1]

[43 FR 60895, Dec. 29, 1978]

§ 520.2345 Tetracycline oral dosage forms.

§ 520.2345a Tetracycline hydrochloride capsules.

(a) *Specifications.* Each capsule contains 50, 100, 125, 250, or 500 milligrams of tetracycline hydrochloride.

(b) *Sponsor.* See §510.600(c) of this chapter for identification of the sponsors:

(1) To No. 000009: 250 milligrams per capsule.

(2) To No. 000069: 125, 250, and 500 milligrams per capsule.

(3) To No. 000115: 50, 100, 250, and 500 milligrams per capsule.

(c) *Conditions of use. Dogs*—(1) *Amount.* 25 milligrams per pound of body weight per day in divided doses every 6 hours.

(2) *Indications for use.* Treatment of infections caused by organisms sensitive to tetracycline hydrochloride, such as bacterial gastroenteritis due to *E. coli* and urinary tract infections due to *Staphylococcus* spp. and *E. coli.*

(3) *Limitations.* Administer orally; continue treatment until symptoms of the disease have subsided and the temperature is normal for 48 hours; not for use in animals raised for food production; Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[57 FR 37327, Aug. 18, 1992, as amended at 59 FR 59365, Nov. 17, 1994; 63 FR 5255, Feb. 2, 1998]

§ 520.2345b Tetracycline tablets.

(a) *Specifications.* Each tablet contains 100, 250, or 500 milligrams of tetracycline (as the hydrochloride).

(b) *Sponsor.* For 100, 250, or 500 milligrams per tablet, see No. 000069 in §510.600(c) of this chapter. For 250 milligrams per tablet, see No. 000009 in §510.600(c) of this chapter.

(c) *Conditions of use. Dogs*—(1) *Amount.* 25 milligrams per pound of body weight per day in divided doses every 6 hours.

(2) *Indications for use.* Treatment of infections caused by organisms sensitive to tetracycline hydrochloride,

[1] These conditions are NAS/NRC reviewed and deemed effective. Applications for these uses need not include effectiveness data as specified by §514.111 of this chapter, but may require bioequivalency and safety information.